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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,619	10/07/2004	Rajamannar Thennati	15395.0011USWO	1765
23552 7590 05/20/2009 MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903				
EXAMINER				
DESAL, RITA J				
ART UNIT		PAPER NUMBER		
1625				
MAIL DATE		DELIVERY MODE		
05/20/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/510,619

Applicant(s)

THENNATI ET AL.

Examiner

Rita J. Desai

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/9/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/9/08 has been entered.

Claims 23- 27 are new and are pending.

Claims 1-22 have been cancelled.

Applicants have amended the claims now to a process of hydrolysis of Loratadiene with methanesulfonic acid to produce desloratadiene. The previous rejection is now withdrawn and a new rejection is made.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO02/42290 Fisher et al in view of Fountoulakis et al and Sigmaaldrich catalogue.

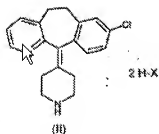
Applicants claims are drawn to a process of making desloratadine from loratadine by hydrolysis using a strong acid such as methanesulfonic acid.

Scope & Content of Prior Art MPEP 2141.01

The prior art on page 4 teaches a process of making desloratadine .

The invention also relates to the synthesis of acid addition salts of formula II, by reacting the loratadine of formula III (chemical name: 8-chloro-6,11-dihydro-11-(1-ethoxycarbonyl-4-piperidylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridine) with concentrated mineral acid.

Formula II is given by



Sulfuric acid is used in the example disclosed.

On page 8 in the table the methane sulphonic salt is also disclosed.

According to the Sigma Aldrich , at sigmaaldrich.com/life-science/life-science-catalog/product-catalog.html?TablePage=22224656 there is teaching that methanesufonic acid makes the hydrolysis faster.

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Products for Amino Acid Hydrolysis

Hydrolysis is typically achieved by acid conditions. A standard procedure is hydrolysis with 6 M hydrochloric acid (24 hours, 110°C). These standard procedure is a compromise between time requirement and temperature. Sensitive amino acids (especially tryptophan and cysteine) will be partially destroyed. Gas phase hydrolysis and addition of other acids (e.g. propionic acid, TFA, methanesulfonic acid) can be used to shorten the hydrolysis time and improve the yield of sensitive amino acids.

Fountoulakis et al teaches that methanesulphonic acid is routinely used for the hydrolysis.

Difference between Prior Art and the claims MPEP 2141.02

The WO reference does not specifically disclose the methanesulphonic acid.

However methanesulfonic acid which is used routinely in organic synthesis for hydrolysis.

Taught by Fountoulakis et al.

Prima Facie Obviousness , Rational and Motivation MPEP 2142-2413

One of skill in the art would be motivated to make the desloratadine, by hydrolysis of the loratadine with methanesulphonic acid. Changing the solvents, and pH of the reaction is within the scope of routine experimentation. Using Methanesulphonic acid for hydrolysis would be obvious to try as one would expect the rate would be faster.

Conclusion

Claims 23-27 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rita J. Desai/
Primary Examiner, Art Unit 1625

March 11, 2009.